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| EXAMINER | |
|---|---|
| ALI, SHUMAYA B | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/665,973 | TRAN ET AL. | |
| | Examiner | Art Unit | |
| | Shumaya B. Ali | 3771 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *17 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *28-35 and 37-44* is/are allowed.

6)☒ Claim(s) *1-27,36,45-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of Claims*

In response to the office action field on 4/4/07, Applicant has amended claims 1,6,7,26-28,33,3439,45,46,47, and 54. Claims 1-54 are pending in the instant application.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-8,10-22,26, and 27 are rejected under 35 U.S.C. 102 (b) as being anticipated by Giba et al. US 5,876,373.**

**As to claim 1, Giba** discloses a catheter **(fig.1, 100)** for delivering a contraceptive device within a fallopian tube, the catheter comprising: an elongate tubular catheter body **(fig.1, 100)** having a proximal **(102)** portion adjacent a proximal end **(proximal end is toward the handle 102, see fig.1)**, a distal portion **(fig.1, 110)** adjacent a distal end **(distal end is toward the elongated tube 110, see fig.1)**, and at least one lumen **(fig.3 depicts that a lumen contains coil 130)**; and at least one coil **(figs.3 and 4, 130)** disposed along the catheter body nearer the distal end than the proximal end and encircling the lumen **(see fig.2)**. Giba's coil is inherently constrained to allow distal portion to have varying degrees of flexibility. Giba's device is fully capable of being adapted to couple a contraceptive device.

**As to claim 2, Giba** discloses a catheter as in claim 1, wherein the distal portion of the catheter body is more flexible towards the distal end of the catheter body than towards the proximal end **(see col.8, lines 15 and 16).**

**As to claim 3, Giba** discloses a catheter as in claim 2, wherein the distal portion of the catheter body comprises multiple layers **(fig.3, 114,120, and 130,)**, and the at least one coil comprises one of the layers **(fig.3 depicts that 130 is a coil layer)**.

**As to claim 4, Giba** discloses a catheter as in claim 3, wherein the multiple layers comprise: an inner layer **(fig.3, 114)**; a middle layer **(fig.3, 130)**; and an outer layer **(fig.4, 120)**.

**As to claim 5, Giba** discloses a catheter as in claim 4, wherein the middle layer comprises the coil **(fig.3 depicts that the middle layer comprises the coil 130).**

**As to claim 6, Giba** discloses a catheter as in claim 5, wherein the coil comprises at least one material selected from the group consisting of nickel-titanium alloy stainless steel, titanium and a polymer **(col.9, lines 63-67)**.

**As to claim 7, Giba** discloses a catheter as in claim 4, wherein the inner layer comprises at least one material selected from the group consisting of polytetraflouroethylene, etched polytetraflouroethylene and a fluoropolymer **(col.9, lines 63-67)**.

**As to claim 8, Giba** discloses a catheter as in claim 4, wherein the outer layer comprises at least one polyurethane material **(col.9, lines 63-67)**.

**As to claim 10, Giba** discloses a catheter as in claim 2, wherein the distal portion comprises: a first segment **(fig.2, 162)**; and at least a second segment **(fig.12, 110)** distal to the first segment, wherein the second segment is more flexible than the first segment **(col.8, lines 15**

**and 16; and coil part 130 in the second segment makes the second segment more flexible than the first segment).**

**As to claim 11, Giba** discloses a catheter as in claim 10, further comprising a third segment **(fig.2, 106)** distal to the second segment, wherein the third segment is more flexible than the second segment **(col.8, lines 15-17)**.

**As to claim 12, Giba** discloses a catheter as in claim 11, wherein the distal portion comprises: an inner layer **(fig.3, 114)**; a middle layer **(fig.3, 130)**; and an outer layer **(fig.3, 120)**.

**As to claim 13, Giba** discloses a catheter as in claim 12, wherein the middle layer comprises the coil **("see a helical coil" in col.9, line 40)** and the outer layer comprises at least one polyurethane material **(col.9, lines 63-67)**.

**As to claim 14, Giba** discloses a catheter as in claim 13, wherein the at least one polyurethane material comprises at least two polyurethane materials for conferring varying levels of flexibility to the distal portion **(see "alloy" in col.9, lines 63-67)**.

**As to claim 15, Giba** discloses a catheter as in claim 13, wherein the at least one polyurethane material has an increasing amount of flexibility from a proximal end of the distal portion to a distal end of the distal portion **(col.9, lines 63-67, and col.10, lines 1-9)**.

**As to claim 16, Giba** discloses a catheter as in claim 1, wherein a pitch of the at least one coil is approximately 0.030 cm **(fig. 10 depicts that coil 130 is approximately 0.030 cm)**.

**As to claim 17, Giba** discloses a catheter as in claim 1, wherein the distal portion of the catheter body has a length of between about 1.2 cm and about 2.0 cm **(fig. 1 depicts that the catheter body 110 has a length of between about 1.2 cm and about 2.0 cm).**

**As to claim 18, Giba** discloses a catheter as in claim 17, wherein the at least one coil has a length of between about 1.6 cm and about 2.4 cm **(fig. 10 depicts that coil 130 has a length of between about 1.6 cm and about 2.4 cm).**

**As to claim 19, Giba** discloses a catheter as in claim 18, wherein the at least one coil extends through at least part of the distal portion of the catheter body and at least part of the proximal portion of the catheter body **(see fig.10)**.

**As to claim 20, Giba** discloses a catheter as in claim 19, wherein a distal end **(fig.1, 156)** of the proximal portion of the catheter body overlaps a proximal end of the distal portion of the catheter body.

**As to claim 21, Giba** discloses a catheter as in claim 18, wherein the length of the catheter body is between about 43 cm and about 50 cm **(fig.1 depicts that the catheter body 100 is between about 43 cm and about 50 cm).**

**As to claim 22, Giba** discloses a catheter as in claim 1, wherein an inner diameter of the proximal portion of the catheter body is smaller near the distal end of the catheter body than near the proximal end **(see fig.1, were the catheter body tapes from proximal to distal, and the inner diameter of 102 is depicted as larger than the inner diameter of 110)**.

**As to claim 26, Giba** discloses a catheter for delivering a contraceptive device within a fallopian tube, the catheter comprising: an elongate tubular catheter body **(fig.1, 100)** having a proximal portion **(fig.1, 102)** adjacent a proximal end **(proximal end is toward the handle 102 and distal end is toward the elongated tube 110, see fig.1)**, a distal portion **(fig.1, 110)** adjacent a distal end **(distal end is toward the elongated tube 110, see fig.1)**, and at least one lumen **(fig.3 depicts that a lumen contains coil 130)**, wherein the distal portion is more flexible

towards the distal end than towards the proximal end **(col.8, lines 15 and 16)**; and at least one coil **(figs.3 and 4, 130)** disposed along the catheter body nearer the distal end than the proximal end and encircling the lumen **(see figs. 3 and 4)**.

**As to claim 27, Giba** discloses a catheter for delivering a contraceptive device within a fallopian tube, the catheter comprising: an elongate tubular catheter body **(fig.1, 100)** having a proximal portion **(fig.1, 102)** adjacent a proximal end **(proximal end is toward the handle 102 and distal end is toward the elongated tube 110, see fig.1)**, a distal portion **(fig.1, 110)** of between about 1.2 cm and about 2.0 cm **(fig. 1 depicts that the distal portion 110 has a length of between about 1.2 cm and about 2.0 cm)** adjacent a distal end **(distal end is toward the elongated tube 110, see fig.1)**, and at least one lumen **(fig.3 depicts that a lumen contains coil 130)**, wherein the distal portion is more flexible towards the distal end than towards the proximal end **(see figs. 3 and 4)**; and at least one coil **(figs.3 and 4, 130)** disposed along the catheter body nearer the distal end than the proximal end and encircling the lumen **(see figs. 3 and 4, 130)**. Giba's coil is inherently constrained to allow distal portion to have varying degrees of flexibility. Giba's device is fully capable of being adapted to couple a contraceptive device.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 7,9,23-25, and 45-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giba et al. US 5,876,373.**

**As to claims 7 and 9, Giba** lacks a catheter as in claim 8, wherein the polyurethane material comprises Carbothane. **However, a close review of Applicant's disclosure suggests that the Applicant has not stated why a particular polyurethane material is critical to the invention in terms of providing a specific function and solving a stated problem. Therefore, one of ordinary skill of art would consider the specific polyurethane material used in the claimed invention as a matter of design choice because the type of polyurethane used would not seem to affect how the catheter would function. Therefore, it would have been an obvious matter of design choice to modify Giba to obtain the invention as specified in claim 7.**

**As to claim 23, Giba** discloses a catheter as in claim 1, wherein the proximal portion of the catheter body comprises at least one polyether block amide. **However, polyether block amide is presented as an alternative material to polyurethane material (see page 6, paragraph 18 of Applicant's specification). Therefore, Giba's teaching of polyurethane**

**material (col.9, lines 63-67 of Giba) is considered an alternative equivalent material to polyether block amide. Thus, Giba teaches an alternative catheter body material that is within the scope of the claimed limitation of "polyether block amide".**

**As to claim 24, Giba** discloses a catheter as in claim 1, wherein the catheter body includes at least one visualization marker **(fig.10, 134)** near the distal portion for enhancing visualization of a proximal-most end of the distal portion **(col.10, lines 38-42), Giba however lacks the maker is located at the proximal portion of the catheter body. However, a close review of Applicant's disclosure suggests that the Applicant has not stated why a particular location of the marker is critical to the invention in terms of providing a specific function and solving a stated problem. Therefore, one of ordinary skill of art would consider location of the marker as a matter of design choice because where the marker is located would not affect how the marker would function. Therefore, it would have been an obvious matter of design choice to modify Giba to obtain the invention as specified in claim 24.**

**As to claim 25, Giba** teaches a catheter as in claim 24, wherein the visualization marker comprises at least one radiopaque material **(col.10, lines 38-42)**.

**As to claims 45-54, Giba** lacks the detailed method steps cited for claims 45-54. **However, Giba teaches structures that are required to perform the method steps cited in claims 45-54 (see rejection cited for claims 1-27). Therefore, it would have been obvious to one of ordinary skill in the art to obtain the method steps as specified in claims 45-54 through the use of Giba's catheter.**

### *Response to Arguments*

Applicant's arguments filed 7/17/07 have been fully considered but they are not persuasive. Applicant argues that Giba does not teach the newly added limitation, i.e. "wherein the distal portion has varying degree of flexibility determined by constraining the coil", however, "flexibility" is driven by a the coil structure. Giba teaches such coil stature, thus, varying degree of flexibility is attained by constraining the coil. Thus, Giba teaches the amended limitation.

### *Allowable Subject Matter*

Claims 28-35, and 37-44 are allowable over the prior art of record.

### *Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-W-F 8:30am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TEENA MITCHELL
PRIMARY EXAMINER

Shumaya B. Ali 10/1/2007
Examiner
Art Unit 3771